US ERA ARCHIVE DOCUMENT

RESUBMISSION

RISK ASSESSMENT & SCIENCE SUPPORT BRANCH

EFFICACY REVIEW -I

ANTIMICROBIAL DIVISION

IN 06/27/97 OUT 07/08/97

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Reviewed by Srinivas Gowda	Date07/08/97
EPA Reg. No. or File Symbol	
LAN Code 4822-UIU.797 Mehle	(A) in
EPA Petition or EUP No.	
Date Division Received	
Type Product	Hospital Disinfectant
MRID No (s)	441860-14
Product Manager	PM 31 (Edwards)
PM Team Reviewer	Barbara Pringle
Product Name	BD1
Company Name	S.C.Johnson & Son, Inc.
Submission Purpose Resubmission	of Residual Self-Sanitizing Data
In response	to Agency letter dated Jun 20 1997
Type Formulation	Liquid Pump Spray
Active Ingredient (s):	<u> </u>
n-Alkyl (60% C14, 30% C16, 5% Condition of the control of the cont	12, 5% C18) ide0.11
n-Alkyl (68% C12, 32% C14) dimethyl ethylbenzyl ammonium o	chloride0.11
3-(trimethoxisilyl) propylmethy:	loctadecyl ammonium chloride.0.11

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202.0 Recommendations

202.1 Efficacy not Supported by the Data:

"Residual Antibacterial Test for Bathroom Duck" by Diane M. Falbo, Technology specialist, S.C. Johnson Wax, Inc., 1525 Howe Street, Racine, Wisconsin 53403, dated December 21, 1996 (MRID No. 441860-14)

The submitted residual self-sanitizing test data are not acceptable for the following reasons:

- 1. Test and control surfaces were not recontaminated with the test inocula with organic soil at 24 hour intervals for up to seven days. See item 9.2.5 of the protocol under the heading "Procedures".
- 2. On day zero and once per day for up to seven days, tiles were rinsed for 5 minutes only instead of 30±5 minutes. See item 9.2.1 of the protocol under the heading "Procedures".
- 3. The 24 hour contact time employed in the test is too long and it does not simulate the real use situation.

NOTE TO PM: In the previous review for this product, the virucidal data for MRID # 441860-11 was accepted by mistake. Comments should read as follows:

"Efficacy Testing of Disinfectant Bathroom Duck - No Fragrance. Formula 7217H121 (BTC 2125M) Virucidal Claims 201M3" by Diane M. Falbo, S.C.Johnson Wax, Inc., 15425 Howe Street, Racine, WI 53403, dated December 1993 (MRID No. 441860-11)

The submitted virucidal data developed by the Modified AOAC Germicidal Spray Products Test Method are not acceptable because insufficient number of embrionated eggs survived virucidal testing for a valid test. Tests must be repeated using a good batch of viable embrionated eggs and a better neutralization procedure. For your information: You must stop the virucidal action immediately after 10 minute contact time by the addition of an appropriate neutralizer solution to the virus + disinfectant mixture prior to resuspension.

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